REMARKS

The Claims

Claims 1-16 and 22-23 are under examination; claims 17-21 were withdrawn as being drawn to a non-elected invention. Claims 5-7 are now canceled, and claims 24-26 have been added by the present amendment.

Claims 1, 3, 22, and 23 are amended; claims 24-26 are new. Support for the claim amendments is found in the specification as follows.

Claim 1: At page 7, ll. 23-25, the specification describes a particularly preferred embodiment wherein the lipidation signal is derived from a bacterium, which facilitates production of the proteinaceous molecule in E. coli.

Claim 3: At page 13, ll. 26-30, the specification describes "enveloped viruses"; thus it refers to a virus enveloped by a cell membrane.

Claim 22: This amendment follows the Examiner's suggestion for clarification.

Claim 23: At page 7, ll. 23-25, the specification describes a particularly preferred embodiment wherein the lipidation signal is derived from a bacterium, which facilitates production of the proteinaceous molecule in E. coli.

Claim 24: At page 7, ll. 15-22, the specification teaches the desirability and advantages of using a prokaryotic host to produce the proteinaceous material, so it can be used to treat a eukaryotic cell. See also original claims 22 and 23: this claim merely adds the 'eukaryotic cell' limitation to the originally filed claims.

Claim 25: The specification describes such genetic modifications at page 15, ll. 19-21.

Claim 26: See page 12, ll. 11-13, where the specification states that treatment of human cells is a preferred embodiment.

Thus the claim amendments add no new matter, and entry of the amended claims is requested.

Priority

The Examiner correctly notes that the priority claim to U.S. Application No. 09/069,534 was made in error. The present application is a continuation of U.S. Application No. 09/418,563, which was filed on 15 October 1999, and is now U.S. Patent No. 6,440,736. The Examiner correctly deduced this, and concluded that the applicable priority date would be 15 October 1999. However, the parent application claims priority to a foreign application, European Application No. 98203482.9, which was filed on 16 October 1998. A claim of priority to the European application has been submitted with a Supplemental Application Data Sheet that was mailed on 13 July 2004. Thus the applicant requests recognition of the corrected priority date of 16 October 1998.

Claim Rejections: 35 U.S.C. § 112

Claims 1-16 and 22-23 were rejected as allegedly indefinite due to the usage of the phrase "derived from", which referred to cell membranes and to a first and a second protein. The Examiner asserts that this implies an indirect process, which renders the nature and number of steps required to obtain the membranes and / or proteins unclear. The Examiner helpfully suggested replacing the term "derived from" with the phrase "obtained from".

The present amendment has adopted the Examiner's suggestion with respect to the membranes of the present claims. However, the applicant has retained the phrase "derived from" in reference to the proteins of the present invention. The proteins of the invention comprise portions originating from at least two different polypeptide sources; one is a lipidation signal from a bacterial protein, but the other may be a natural protein such as a membrane-associated protein as described in the specification at page 8, ll. 23-34, or it may be a non-natural protein as described on page 9, ll.

4-6. It may originate from proteins of the immune system as described on page 9, ll. 22-28. It also may include a second lipidation signal, or a purification tag, or a detection tag, or all of the above, as described on page 10. The proteinaceous molecules are thus derived from portions of proteins having various origins, and may be produced by genetic engineering techniques well known to those of ordinary skill in the art. They are, for example, produced in bacteria as described on pages 21-22.

The proteinaceous molecules of the invention are thus not "obtained from" the protein where they originated; they are generally produced by a multi-step process that involves gene splicing followed by translation of a DNA sequence into a polypeptide in a host organism. See page 23, which describes production of a DNA construct comprising a scFv sequence, a lipidation signal, a linker, a myc tag for detection, and a polyhistidine tag for purification, which was expressed in an E. coli strain; the modified scFv was then harvested from the bacteria and purified by chromatography. The applicant thus considers the phrase "derived from" to be aptly descriptive of the proteins of the invention, and to be adequately supported by the specification. The process by which the proteinaceous materials are obtained is sufficiently indirect to warrant use of the phrase "derived from", but the meaning of that phrase would be well understood by those of skill, especially in light of the specification.

Claim 22 was alleged to be indefinite due to usage of the term "obtainable by". The claim has been amended to recite that the claimed cells are "obtained by" the process of claim 1. The applicant believes this eliminates any lack of clarity in the metes and bounds of the claim. The rejections based on 35 U.S.C. § 112 can thus be withdrawn.

Double Patenting

The Examiner alleges that the present claims are not patentably distinct from the claims allowed in U.S. Patent No. 6,440,736, and rejects the claims under the judicially created doctrine of obviousness type double patenting.

The present application is commonly owned with U.S. Patent No. 6,440,736; thus a timely filed Terminal Disclaimer will overcome this rejection. Accordingly, a Terminal Disclaimer is included herewith. This ground for rejection may thus be withdrawn.

Claim Rejections for Anticipation: 35 U.S.C. § 102.

Claims 1-2, 4-5, 7-9, 11-12, 14-16, and 22-23 are rejected under 102(b) as being anticipated by Tykocinski, et al., WO 96/12009 A2. Tykocinski, according to the Examiner, teaches "a process comprising contacting the cell or membrane with a lipid-modified proteinaceous molecule, where the lipid-modified proteinaceous molecule comprises at least one protein moiety derived from a first protein and at least one lipidation signal derived from a second protein."

Tykocinski teaches that GPI-modified chimeric proteins can be used to add immunologically active proteins to a cell surface. It also says that other lipid-attachment methods, "for example, chemical coupling of a lipid moiety directly to the MHC polypeptide" could be used. Tykocinski, at 10. The reference then asserts that GPI (glycosyl phosphatidyl inositol) modification has certain advantages. It is site specific, unlike chemical modification methods known in the art, and "the peptide:anchor link is natural and hence is less likely to be immunogenic." Id. Thus Tykocinski, which is entitled "Methods for Engineering Antigen-Presenting Cells", relates only to manipulating immune responses: it discloses only the use of GPI to anchor MHC polypeptides to cell membranes, and teaches that selection of a lipid tail for such anchoring purpose should be driven by its immunogenic potential.

The present claims are drawn to a proteinaceous molecule having a lipidation signal that is specifically derived from a bacterial protein. GPI is a known lipophilic anchor for proteins in eukaryotic cells as suggested in the specification (lipidation with GPI "is achieved in eukaryotic cells, preferably yeast cells." –page 8, ll. 16-17). The Tykocinski reference suggests that its use is advantageous to avoid immunogenic responses. Thus Tykocinski discloses only GPI as a lipid tag, and teaches away from the use of a lipidation signal derived from a non-eukaryotic source. Therefore, the reference does not anticipate the present claims: it neither discloses nor suggests the

use of a lipidation signal from any prokaryotic source. The Examiner appears to recognize this in *not* rejecting claim 6, which was drawn to a process using a bacterial lipoprotein-derived lipidation signal.

Furthermore, the applicant notes that the reference provides motivation to consider only eukaryotic lipid tags for the purpose of adding proteinaceous molecules to a cell membrane. Based on this reference, one of ordinary skill modifying the work of Tykocinski would seek alternative lipidation tags in other eukaryotic organisms rather than in a prokaryotic bacterium. The present specification teaches the advantages of producing the lipid-modified proteinaceous molecule of the invention in a bacterium rather than a eukaryotic cell, including higher yields, better cost effectiveness, and less propensity for prion or virus contamination of the proteinaceous product. Specification at page 7, ll.13-22. Obviously, production of a lipid-modified proteinaceous molecule in bacteria requires a lipidation signal that is recognized by the lipidation machinery of the host cell, so that lipidation occurs; thus a bacterial lipidation signal is advantageous. The cited reference does not suggest or disclose these factors, only teaching reasons *not* to use bacterially-derived lipidation signals. Thus the reference does not anticipate *or* render obvious the present invention, and the rejection of claims based on Tykocinski can be withdrawn in light of the present amendment.

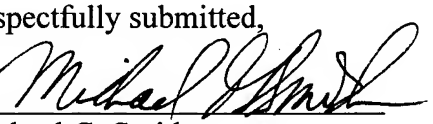
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for immediate allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 313632000801. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: November 17, 2004

Respectfully submitted,

By 

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